

Remarks

The Examiner is thanked for the Office Action mailed 12/24/2002. The objections and rejections are discussed below.

The Examiner first objected to Claim 1 for use of two paragraph “(d)”, and to claim 10 for being the same as claim 3. Claim 1 has been amended to replace the second “(d)” with “(e)”, and claim has been amended to refer to “claim 8”, both as suggested by the Examiner. The Examiner is thanked for noting these errors.

Claims 1-14 are presently under consideration in the application. Claims 1 and 8 are the only independent claims in this group.

The Examiner next rejected claims 1-14 under 35 U.S.C. 112, first paragraph for lack of enablement. The Examiner stated that while the claims were enabled for generating an addressable array of biopolymers on a substrate via ink jet head fabrication, they do not reasonably provide enablement for generating an addressable array via *any* fabrication method. In discussing the rejection the Examiner referenced different chemistry required for different techniques, including *in situ* such as photolithographic techniques. However, both claims 1 and 8 having nothing to do with *in situ* synthesis of any kind. In particular, both claims recite receiving biopolymers in vessels and depositing these received biopolymers onto the substrate. There is no synthesis involved but instead the received biopolymers are “deposited” onto the substrate.

Bearing in mind what the claims actually cover, the question then becomes whether depositing biopolymers onto a substrate to fabricate an array as claimed, is reasonably enabled by the present specification. As pointed out in M.P.E.P 2164.08:

“The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of the enablement involves two stages of inquiry. The first is to determine how broad the claim is with respect to the disclosure. The entire claim must be considered. The second inquiry is to determine if one skilled in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation.”

On the first stage of the inquiry, as discussed above the rejected claims involve depositing obtained biopolymers onto the substrate to form an array. The second

stage then involves the question of whether undue experimentation is required to do this. On the question of whether experimentation is "undue", as pointed out in M.P.E.P. 2164.06 a considerable amount of experimentation is permissible if it is routine:

"'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.' " *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). Time and expense are merely factors in this consideration and are not the controlling factors. *United States v. Telectronics Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989)."

Considering the claims again, all that is required is to deposit the biopolymer to form the array. Binding is not even required since one could use depressions in the surface to localize the biopolymers to their respective regions. Even if it was desired to provide binding of the deposited biopolymer to the substrate, binding of one thing to another is the most routine type of experimentation a chemist can undertake. All that is required is that the chemist deposit the biopolymer onto the surface of interest and see if it adheres thereto under the conditions of use. If not, the surface can be modified and/or the biopolymer modified with a great many well known surface modifiers or linking groups and the experiment repeated. This is highly routine. Further, the state of the art indicates that one of ordinary skill in the array art is expected to be able to perform such routine experimentation. **For example**, the following U.S. patents have claims requiring binding of deposited biopolymers (or even broader classes of compounds) but without reciting much detail in the way all possible different bindings might take place: 6,083,763 (Balch); 6,001,309 (Gamble et al.); 5,658,802 (Hayes et al.); 5,807,522 (Brown et al.); 5,314,820 (Coles). Nor can the Examiner ignore such patents since as stated by the Board in Ex Parte D 27 USPQ2d 1067 (BPAI 1993) @ 1069, a U.S. patent :

"is a domestic patent and, therefore, is imbued with a legal presumption of correctness under 35 U.S.C. 282 (citations omitted)"

Accordingly, given the actual scope of the claims under consideration and the above, the present rejection should be withdrawn.

The Examiner next rejected claims 1-14 under 35 U.S.C. 112, second paragraph as being indefinite. First, on the question of what is required by 35 USC § 112, second paragraph, the Federal Circuit's discussion in Miles Laboratories Inc. v. Shandon Inc., 27 USPQ 1123 @ 1126 (Fed.Cir. 1993) is instructive:

"The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. *Orthokinetics*, 806 F.2d at 1576. If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more. *Hybritech*, 802 F.2d at 1385. The degree of precision necessary for adequate claims is a function of the nature of the subject matter. *Id.*"

Further, M.P.E.P. § 2173 outlines the same approach when considering the second paragraph of 35 USC § 112.

The Examiner first stated that it was unclear what is meant by "regions". The Merriam-Webster On-Line Dictionary (available at www.merriam.com) contains a number of definitions of "region" only number six of which is relevant:

"6 : an open connected set together with none, some, or all of the points on its boundary <a simple closed curve divides a plane into two *regions*>"

Further, page 8, lines 2-6 state the following:

"An array is "addressable" in that it has multiple regions of different moieties (for example, different polynucleotide sequences) such that a region (a "feature" or "spot" of the array) at a particular predetermined location (an "address") on the array will detect a particular target or class of targets (although a feature may incidentally detect non-targets of that feature)."

Thus, each "region" detects a particular target or class of targets. Given the dictionary definition and the above, one of skill in the art then, is at least "reasonably apprised" of the scope of the claimed invention (i.e. if there are different "regions" which detect particular targets or classes of targets then these fall under the language of the claim. Accordingly, since one of skill is at least "reasonably apprised" of the claim scope, this rejection should be withdrawn.

The Examiner next rejected claims 5, 6, 12, 13 as indefinite on the use of the phrase "portable storage medium" and alleged that this could encompass any object

containing another object that is moved from one location to another. However, this ignores the other language of the claims which specifically refers to a “memory” (into which data can be saved) comprising a portable storage medium. Thus, the portable storage medium is a memory into which data can be saved and retrieved. Note also in this context that the only relevant definition of a “memory” in Merriam-Webster’s On-Line Dictionary is as follows:

“4 a : a device or a component of a device in which information especially for a computer can be inserted and stored and from which it may be extracted when wanted b : capacity for storing information <four megabytes of memory>

Thus, one of skill in the art is more than “reasonably apprised” that if the portable device is a memory, it is one which falls within the claims. Accordingly, the present rejection should be withdrawn.

The Examiner next rejected claims 1-5, 7-11, and 13-14 under 35 U.S.C. 103(a) over Cozzette et al., in view of Gamble et al., Coles, Shakib et al, Brown et al., and Balaban et al. First, as the Examiner is well aware, the Examiner bears the initial burden of establishing a case of *prima facie* obviousness. This was set out, for example, by the Federal Circuit in In re Rijckaert 28 USPQ2d 1955 (Fed. Cir. 1993) @ 1956:

“In rejecting claims under 135 USC § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. (citations omitted) Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant.”

In the present case, even assuming that the references contain a suggestion for combining them in the manner advanced by the Examiner, the claimed invention is still not obtained and thus the Examiner has not satisfied her burden of establishing a *prima facie* case of obviousness. Turning to claim 1, for example, this claim requires among other elements the following:

- (a) obtaining the biopolymers from individual identified vessels;
- (b) depositing the biopolymers onto different regions of the substrate so as to fabricate the array;

(c) saving in a memory a map of the identity of the vessels to the corresponding regions of the substrate onto which the biopolymers from respective vessels are deposited, in association with a map identifier;

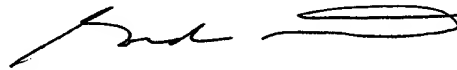
In the combination alleged by the Examiner (in particular, at Page 10 in the Action) there would be an identifier on the substrate which identifies the array and the layout of the array. The Examiner has not pointed to anything in the prior art which discloses or suggests obtaining the biopolymers from individual identified vessels, and forming a map of the identity of the vessels to the corresponding regions of the substrate. None of the cited references deals with or suggests the problem or solution of obtaining biopolymers from individual identified vessels then having to identify these to an end user. While the Examiner at the end of page 10 seems to be making a broad allegation of obviousness in this regard, this reconstruction of the presently claimed invention does not substitute for the requirement to point to a suggestion, for these claimed features in the prior art. The Examiner has not pointed to a suggestion for those claimed features in the prior art and hence has not established a *prima facie* case of obviousness.

If the Examiner intends to rely upon “well known” array fabrication art (such as the referenced microarrays of Affymetrix), or “well known” art for identification such as barcoding (such as the referenced Federal Express or United Parcel Service art), for the features of paragraph (a) or (c) above, the Examiner is specifically requested to identify the art relied upon and either cite the reference or provide an Affidavit of personal knowledge with the relevant details of the suggestion (in accordance with the procedure under M.P.E.P. 2144.03). As stated by the Federal Circuit in In re Lee, 61 USPQ2d 1430 (CAFC, 2002) @ 1435:

“Thus when they rely on what they assert to be general knowledge to negate patentability, that knowledge must be articulated and placed on the record.”

Accordingly, in view of the above amendments and discussion it is believed claims 1-14 are now in condition for allowance. If the Examiner is of the view that there are any outstanding issues which might be resolved by means of a telephone conference, she is invited to call Gordon Stewart at (650)485-2386.

Respectfully submitted,



Gordon M. Stewart
Attorney for Applicants
Reg. No. 30,528

Agilent Technologies, Inc.
Legal Department, DL429
IP Administration
P.O. Box 7599
Loveland, CO 80537-0599